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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/879,165 | 06/13/2001 | Yoshio Fujii | H6810.0026/P026 | 3658 |
| 24998 | 7590 | 02/05/2004 | EXAMINER | |
| DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP | | | COLE, MONIQUE T | |
| 2101 L STREET NW | | | ART UNIT | |
| WASHINGTON, DC 20037-1526 | | | PAPER NUMBER | |
| | | | 1743 | |
| DATE MAILED: 02/05/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,165

Applicant(s)

FUJII ET AL.

Examiner

Monique T. Cole

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 10-23 and 30-33 is/are rejected.
- 7) ☒ Claim(s) 4-9 and 24-29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. Most notably, the word "plurality" has been misspelled at several instances.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 3, 10, 21, 22, 23, 30, 31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 4,133,753 to Takeuchi et al. (herein referred to as "Takeuchi").

Takeuchi teaches a method of separation of amino acid constituents wherein amino acids are supplied to a separation column and different elutes of different compositions are supplied to the separation column in succession and stages. The lithium ion concentration is set to no more

than 0.3 M at a time prior to β -aminoisobutyric acid elution and the analysis is displayed via a chromatogram.

It is noted that instant claims 1, 2, 3, 10 and 31 are directed to a computerized method of analysis. However, as only the preamble of the claims recites this limitation and the body of the claim does not require any additional steps that cannot be performed manually, it is the Examiner's position that "computerized" does not add a patentable limitation to the instant claims. Moreover, it has been held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 2, 3, 10-20, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takeuchi in view of USP 3,649,203 to Schneider (herein referred to as "Schneider").

Takeuchi teaches a method of separation of amino acid constituents wherein amino acids are supplied to a separation column and different elutes of different compositions are supplied to the separation column in succession and stages. The lithium ion concentration is set to no more than 0.3 M at a time prior to β -aminoisobutyric acid elution and the analysis is displayed via a chromatogram.

Takeuchi differs from the instantly claimed invention in that it does not disclose the presence of a computer in the chromatography method and does not disclose any components of the apparatus used to perform the chromatography.

Schneider teaches an amino acid analyzer having an ion exchange column similar to that of Takeuchi (abstract). The analyzer is automatically controlled and permits uninterrupted continuous operation of the analyzer without the necessity of operator attention (abstract). The analyzer also has the advantage of having a timing control 11 to ensure that the amino acid analysis is carried out in accordance with a predetermined time sequence. The apparatus comprises containers for supplying the buffer solution 31 & 32; a control and selection valves 8, 9 & 29; a separation column 7; and a central time control mechanism (processor) 11 that automatically effects movement of the various components of the analyzer to complete an analysis of a sample in a predetermined time sequence.

It would have been obvious to one of ordinary skill of the art to automate the method in Takeuchi by using an apparatus such as that taught by Schneider because the goals of the two processes are similar and Schneider teaches an advantageous apparatus that eliminates operator attention and increases the accuracy of the analysis by strict adherence to predetermined time sequences. Takeuchi emphasizes the importance of strict timetables in accordance with its multistage process (col. 6, lines 18-21) and an apparatus such as that taught by Schneider would facilitate the accomplishment of the goals set in Takeuchi.

With regard to what the processor is programmed for in claims 11 and 32, a claim containing "a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus." Thus, the claim limitations directed to the amino acid analysis are of no consequence. With regard to dependent claims 12-20, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. All of the claims serve to define the process and add to structural significance to the claimed invention. See MPEP 2114.

Allowable Subject Matter

8. Claims 4-9 and 24-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


9. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or reasonably suggest the elution parameters set forth in the aforementioned claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 571-272-1255. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.


Monique T. Cole
Examiner
Art Unit 1743

MC